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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,569	02/21/2002	Gholam-Reza Zadno-Azizi	38349-0102D	4156

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HELLER EHRMAN WHITE & MCAULIFFE LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,569	ZADNO-AZIZI ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13,15*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/20/03 has been entered as Paper No. 16. The change made to claim 23 has been approved by the examiner, and new claims 26 and 27 have been added. All the currently pending claims are being considered for further examination on the merits, and include claims 16-27.

2. The declaration filed on 10/20/03 under 37 CFR 1.131 is sufficient to overcome the Knapp et al. (USPN 5,984,965) reference.

3. The declaration under 37 CFR 1.132 filed 10/20/03 is sufficient to overcome the rejection of claims 16-19 based upon 35 U.S.C. 112, first paragraph.

Response to Arguments

4. Applicant's arguments, see pages 6-10, filed 10/20/03, with respect to the rejection(s)of claim(s) 16-19 under 112, first paragraph have been fully considered, and in addition to the Declaration under C.F.R. 1.132, are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Leonhardt et al. (see below). This is a non-final rejection.

Claim Objections

5. Claims 21 and 24 are objected to because the limitation of "outer diameter of 0.349 inches" is not commensurate in scope with the specification, which discloses the outside diameter as *approximately* 0.349 inches (page 7, line 6). The examiner suggests inserting

--approximately-- before "0.349" in both claims 21 and 24. Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 26 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Currently, the outer surface is claimed as sealing with an interior of a body passageway. The interior of a body passageway is non-statutory subject matter. The examiner suggests changing "seals" to --is configured to seal--.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 16-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (USPN 5,957,949 as cited in applicant's IDS) in view of Andersen et al. (USPN 5,411,552 as cited in applicant's IDS).

Independent claims 16, 17, 18 and 19 require the structural limitations of an obstructing member being a one-way valve and having an outer dimension sized to make continuous contact with and seal with a bronchial sub-branch. Independent claims 17 and 19 require the additional

limitations of a conduit and the obstructing member being dimensioned as to be guidable through the conduit. Leonhardt et al. discloses a obstructing member (valve stent) with all the elements of claims 16, 17, 18 and 19, but is silent to the obstructing member having an outer dimension sized to make continuous contact with and seal with a bronchial sub-branch. See Figure 4 and column 3, lines 32-33 for an obstructing member (20) being a one-way valve (22). See Figure 7A and column 6, lines 55-61 for a conduit (106) and the obstructing member (20) being dimensioned to be guidable through the conduit. See column 1, lines 11-15 for the obstructing member being placed anywhere flow control is desired and columns 4-5, lines 63-5 for the obstructing member conforming to and sealing against the body lumen in which it is deployed. Andersen et al. teaches replacing insufficient valves within the pulmonary artery with replacement valves in order to restore proper functioning of the pulmonary artery by reestablishing one-directional flow therein. See column 3, lines 43-46. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Andersen et al. to dimension the obstructing member of Leonhardt et al. for placement within a pulmonary artery suffering from valvular insufficiency in order to restore uni-directional flow within the pulmonary artery. The size of the human pulmonary artery ranges from about 5mm in an infant up to about 35mm in a full sized adult. On page 4, section 12 of the "Declaration of Antony Fields Under 37 C.F.R. 1.132", it is admitted that the sub-branch of a human bronchial passageway can have an average diameter of up to about 9.10 ± 2.05mm. Because there is an overlapping in size between the pulmonary artery and the bronchial sub-branch, it is obvious that the obstructing member of Leonhardt et al., when sized to be used in the pulmonary artery, will also be dimensioned to be used in the bronchial sub-branch.

When used in the bronchial sub-branch, the outer dimension of the obstructing member will make continuous contact with and seal the inner dimension of the bronchial sub-branch, thereby enabling and resulting in all the required functional limitations.

Leonhardt et al. discloses a fluid-flow control device and system with all the elements of claims 20, 23, 26 and 27, but is silent to the one-way valve being dimensioned for pulmonary placement. See column 1, lines 11-15 for a one-way valve (20) configured to restrict fluid flow (claims 20, 23, 26 and 27). See Figure 7A for an outer sheath (106) for positioning a valve and the one-way valve dimensioned to be guidable into the outer sheath (claim 23). See columns 4-5, lines 63-5 for the outer surface of the device sealing with an interior of a body passageway (claim 26). See columns 10-11, lines 61-7 for an elongate passage (54) for positioning a valve and the one-way valve dimensioned to be guidable on the elongate passage (claim 27). See column 1, lines 11-15 for the obstructing member being placed anywhere flow control is desired. Andersen et al. teaches replacing insufficient valves within the pulmonary artery with replacement valves. See column 3, lines 43-46. This replacement restores proper functioning of the pulmonary artery by reestablishing one-directional flow therein. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Andersen et al. to dimension the valve of Leonhardt et al. for pulmonary placement in order to, upon implantation in a pulmonary artery suffering from valvular insufficiency, restore uni-directional flow within the pulmonary artery.

Leonhardt et al., as modified by Andersen et al., does not disclose expressly that the valve has an outer diameter of 0.349 inches (8.8646mm), as required by claims 21 and 24. However, it appears in column 1, lines 11-15 that the valve stent of Leonhardt et al. will be

dimensioned to specifically fit the body passage it is being implanted into to treat, including vascular passages. Because the diameter of the pulmonary artery varies from person to person, and ranges from about 5mm in an infant up to about 35mm in a full size adult, the correct size valve will also vary from person to person. Therefore, it would be obvious to one of ordinary skill in the art to make the valve of Leonhardt et al. and Andersen et al. have an outer diameter of 0.349 inches if that is the correct dimension for the patient.

Claims 22 and 25, see Figure 4 for a valve body (22) having a slit (junction between leaflets) through which fluid can flow (when opened).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 16-22 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,954,766 (cited in applicant's IDS) in view of Andersen et al. (USPN 5,411,552 as cited in applicant's IDS) and over claims 1 and 7 of U.S. Patent No. 6,632,243 in view of Andersen et al. (USPN 5,411,552 as cited in applicant's IDS). The patents claim a fluid-flow control device comprising an outer

surface configured to seal with an interior of a body passageway and a one-way slit valve. Andersen et al. teaches the additional limitation of the valve being dimensioned for pulmonary placement in order to, upon implantation in a pulmonary artery suffering from valvular insufficiency, restore uni-directional flow within the pulmonary artery. See column 3, lines 43-46. Because there is an overlapping in size between the pulmonary artery and the bronchial sub-branch, it is obvious that the obstructing member of Leonhardt et al., when sized to be used in the pulmonary artery, will also be dimensioned to be used in the bronchial sub-branch.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blackshear et al. (USPN 3,667,069) discloses that average diameter of the pulmonary artery is about 1 to 2.5cm. Ruiz (USPN 5,868,779) discloses that the pulmonary artery has a diameter between 15 and 35mm. Ruiz (USPN 5,954,765) discloses that the pulmonary artery in an infant doubles in size within the first twelve months and continues to increase in diameter throughout the first decades of the child's life.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

Urmi Chattopadhyay

Art Unit 3738

David H. Willse
Primary Examiner